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(54) Implantable tubular prosthesis having cuffs

(57) An implantable tubular prosthesis having cuffs adapted to accommodate stents. The prosthesis includes a hollow tubular conduit with cuffs at each end. Each of the cuffs has a closed end and a open end to create a slot for housing the stents. The prosthesis may be an implantable tubular intraluminal prosthesis for insertion within a body vessel, where the hollow tubular conduit is radially expandable to buttress the body vessel. Alternatively, the prosthesis may be an implantable tubular prosthetic graft for surgical replacement of damaged or diseased existing body vessels. The tubular prosthesis and stent combination may be radially expanded so that the stents anchor the prosthesis within the lumen. The slots which house the stents, prevent contact between the stents and fluids flowing through the body vessel.

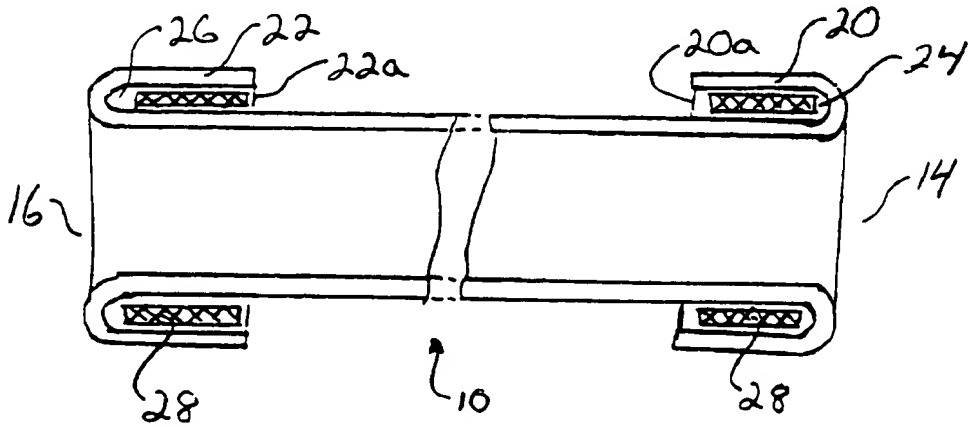

FIG 4

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Description

FIELD OF THE INVENTION:

The present invention relates generally to an implantable tubular prosthesis. More particularly the present invention relates to an implantable tubular prosthesis adapted to accommodate stents for supporting the prosthesis.

BACKGROUND OF THE INVENTION:

The implantation of synthetic tubular prostheses to replace or buttress damaged or diseased vascular vessels or other luminal passageways within the human body is known. Synthetic tubular prostheses include grafts as well as endoprosthetic devices.

Tubular prosthesis such as grafts, are typically implanted by surgical techniques. The surgeon would suture the graft in place in the blood vessel or other body passageway. Other endoprosthetic devices may be implanted intraluminally. These devices may be inserted percutaneously by use of a delivery catheter. Obviously, percutaneous catheter delivery permits implantation of a prosthesis without the need for major surgical intervention and the risks inherent therewith. The art therefore is moving toward the increased use of intraluminal implantation of various prosthetic devices. It has been found that under certain conditions, grafts as well as endoprosthetic devices may be implanted by means of a delivery catheter.

With respect to grafts and other prostheses which may be traditionally surgically implanted, means other than suturing must be found to secure these prostheses in place in the body passageway in order to effectively permit intraluminal implantation. It has been known to employ stents in combination with grafts and various other prostheses to support and secure a prosthesis in place in the body passageway after implantation. Stents are typically radially expandable and/or contractible support members which are positioned inside of the graft or other tubular prosthesis and once the tubular prosthesis is properly positioned, the stent would be expanded to anchor the prosthesis within the body passageway.

However, the use of stents to anchor prostheses is not without problems. Stents sometimes migrate with the flow of body fluid within a vessel if undersized or underexpanded. Also, thrombosis or fibrin buildup may occur within the stent diminishing patency of the intraluminal passageway when the stent is in direct contact with the blood.

U.S. Patent No. 5,151,105 discloses an implantable, collapsible tubular prosthesis, i.e., graft, for surgical implantation within a vascular organ. The ends of the prosthesis include collapsible circular stents or annular balloons affixed thereto. The stents expand to seal the ends of the endo-vascular prosthesis to the inner luminal surface of the blood vessel into which the prosthesis is implanted. The stents may be sutured to the interior wall such that they are in direct contact with the body fluid therein, or may be placed within annular pockets. Because of the nature of the placement of the stent within the annular pocket, the insertion must take place before implantation. If problems arise surrounding the size of the stent, the tubular prosthesis into which the stent has been sealed must be replaced with a more closely fitting stent.

U.S. Patent No. 4,728,328 discloses an implantable tubular prosthetic graft having prosthesis cuffs formed on distal ends of the graft. The cuffs are formed by folding the edges of the graft back over itself and bonding the turned back edges to the graft body. These cuffs are then used to suture the graft to the host vessel. Under certain conditions, however, grafts require greater support than that afforded by merely suturing through cuffs positioned at opposite ends of such graft. Also, the need for suturing would preclude catheter delivery.

Accordingly, there is a need for an implantable tubular prosthesis which overcomes the aforementioned shortcomings of the prior art and provides a universal fitting means for cooperatively employing a stent in combination with the tubular prosthesis.

According to one aspect of the present invention, there is provided an implantable prosthesis comprising:

a tubular conduit having an elongate body and opposed open ends, the conduit being capable of radial diametrical change between a first diameter and a second diameter;

an elongate cuff formed at one end region of the body; and

a variable diameter generally annular stent supported by the cuff.

According to another aspect of the present invention, there is provided a prosthesis for implantation within a body lumen comprising:

an elongate radially expandable tubular body;

a pair of cuffs, one cuff formed at each end region of the body; and

a pair of radially expandable stents, one stent being resident in each cuff of the pair of cuffs.

Preferably the or each cuff defines a partial enclosure with the body for enclosing the stent(s). Conveniently, the or each cuff has a closed end and an open end, thereby defining a slot for insertable accommodation of the stent.

If desired, the tubular conduit includes a plurality of longitudinal ribs to permit radial contraction from the first diameter to the second diameter, to provide for intraluminal deployment. Moreover, conveniently the variable diameter stent is radially collapsible to permit intraluminal deployment thereof.

Preferably the tubular conduit is radially expandable from the second diameter to the first diameter after the intraluminal deployment, and the stent is radially expandable after the intraluminal deployment.

The tubular conduit may be formed of a textile fabric; or may be formed from polytetrafluoroethylene.

The stent may be formed of a wire mesh.

Conveniently the cuff is integrally formed with the tubular conduit, preferably with one or each end region of the tubular conduit being folded back, preferably externally, upon the body to form the cuff(s).

Preferably the cuff is compliant to accommodate a stent within a range of different stent sizes.

The present invention may include an implantable tubular prosthetic graft or may include an endoprosthetic or intraluminal device.

The prosthesis of the present invention may be used in a method of implanting a prosthesis in a body vessel, comprising:

providing an elongate tubular conduit having a cuff at one end thereof;

implanting the tubular conduit in the body vessel;

inserting the stent in the cuff; and

expanding the stent within the cuff to anchor the one end of the tubular conduit in the body vessel.

The prosthesis of the present invention may be used in a method of repairing a damaged location of a body vessel, comprising the steps of:

providing an elongate tubular conduit having cuffs at the ends thereof;

providing a pair of expandable stents;

implanting the tubular conduit in the body vessel whereby the tubular conduit spans the damaged location;

inserting the stents in the cuffs; and

expanding the stents within the cuffs to anchor the tubular conduit in the body vessel adjacent each side of the damaged location.

The implanting step may include intraluminally delivering the tubular conduit.

The inserting step may include intraluminally delivering the stent(s) to the cuff(s), and the inserting step may precede the implanting step, or the implanting step may precede the inserting step.

The method may, wherein the tubular conduit is radially expandable, further include the step of radially expanding the tubular conduit.

The method may further include, prior to the delivery step, collapsing the conduit.

For a better understanding of the present invention and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

Figure 1 is a perspective showing of a synthetic tubular prosthesis;

Figures 2 and 3 are side elevational and front views respectively of a stent used in accordance with the present invention;

Figure 4 shows, in longitudinal cross-section the tubular prosthesis of figure 1 supporting a pair of stents shown in Figures 2 and 3;

Figure 5 is a side elevational view of the combination shown in Figure 4;

Figure 6 is a partial perspective showing of the prosthesis of Figures 4 and 5 shown in a partially collapsed condition; and

Figure 7 is a partial sectional showing of the tubular prosthesis of the present invention implanted within a body vessel.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS:

The implantable tubular prosthesis having integral cuffs of this invention may be used as an intraluminal conduit or endoprosthesis for percutaneous implantation within a diseased or damaged blood vessel or other like vessel to provide reinforcement and support to the vessel. The implantable tubular prosthesis may also be used as a vascular graft to replace damaged or diseased portions of blood vessels or like fluid passageways. The present invention contemplates catheter delivery of the prosthesis, however the invention is not limited thereto.

Referring to Figure 1, an implantable tubular prosthesis 10 is shown. Prosthesis 10 includes tubular conduit 12 having first and second ends 14 and 16 and a tubular channel 15 therebetween. Tubular prosthesis 10 may be a textile member formed from braided, knitted or woven synthetic yarns. Additionally, extruded tubes made from polytetrafluoroethylene (PTFE) and the like may also be used. Preferably the prosthesis 10 may be formed from a polymer material such as polypropylene. While the above-described materials are examples of materials used to form tubular prosthesis 10, it is of course understood that the present invention may be formed of any suitable material. As will be described in further detail hereinbelow, tubular prosthesis 10 may be radially compressed from the structure shown in Figure 1 so as to permit insertion into a delivery catheter for implantation within a body passageway such as a blood vessel, whereupon the prosthesis is expanded to its original form for secure deployment therein. Alternatively, tubular prosthesis 10 may be constructed to be of expandable material so that it is catheter-insertable in its original state and once positioned within the body passageway may be radially expanded (or radially self-expanded) for deployment in the vessel.

Referring now to Figures 2 and 3, a stent 28 is shown. Stent 28 is generally an annular member capable of radial expansion between a first diameter and a second diameter different from the first diameter. Stents such as these are well known in the art may be formed from materials such as stainless steel or other metals or alloys, polymeric materials or composites of polymers and metal and may be shaped in the form of springs, helically-wound coil springs, wire mesh or other structures and configurations. Coil springs and the like may also be manufactured from any expandable heat-sensitive material.

For example, U.S. Patent No. 4,655,771 discloses an expandable device made from woven stainless steel wire. Another example of an expandable stent is dis-

closed in U.S. Patent No. 3,868,956. The stent disclosed therein that is formed with a specific type of metal alloy displaying a memory function. That is, the alloy with which the stent is formed has the ability when compressed to recover its initial non-compressed shape upon heating. Such a stent can be compressed, inserted into and transported within a blood vessel to a desired position. Once in position, the stent can be heated for expansion to its original non-compressed state.

In the present illustrative embodiment, a wire mesh stent is shown. The stent 28 is capable of being radially compressed from the condition shown in Figures 2 and 3 so that it may be intraluminally deployed along with or subsequent to insertion of tubular prosthesis 10. While a compressible stent is shown, it is contemplated that a stent which is radially expandable from an original state may also be employed.

In the preferred embodiment of the present invention tubular prosthesis 10 includes longitudinally extending ribs 18 (Figure 5) to permit folding or radial contraction thereof for insertion of the prosthesis 10 into a blood vessel or other bodily passageway using a catheter, not shown. Although not shown in Figure 1, the tubular conduit 12 may also be formed with one or more longitudinal crimps, creases or the like to enable folding for insertion of the prosthesis into a blood vessel via a catheter.

Referring now to Figures 4 and 5, in accordance with the present invention tubular prosthesis 10 includes a pair of cuffs 20 and 22 disposed respectively adjacent ends 14 and 16. The cuffs 20 and 22 may be free standing cuffs, formed by folding the ends of the tubular conduit 12 back externally over itself. It is also contemplated that the cuffs may be formed by turning inwardly the ends of conduit 12. The cuffs 20 and 22 may also be formed of separate, distinct portions of synthetic material which may be glued or sutured onto tubular conduit 12. Further, the cuffs may comprise a material, such as an elastomeric material that is different than the material comprising the conduit. Cuffs 20 and 22 include inwardly directed open ends 20a and 22a respectively which are wholly unobstructed for stent insertion. Open ended slots 24 and 26 are defined between the external surface of tubular conduit 12 and the internal surface of cuffs 20 and 22. The slots 24 and 26 house one or more stents, such as stent 28, used by the device to both support and seal the body vessel into which the tubular prosthesis 10 is inserted. The stents 28 may be used whether the present invention is used as an implantable prosthetic graft or an endoprosthesis.

The accommodation of stents 28 within the slots 24 and 26 of tubular prosthesis 10 helps assure patency of the lumen of a blood vessel or other body passageway into which the prosthesis 10 is inserted at the exact place at which support is required. The prosthesis/stent combination assures a secure anchor of the prosthesis 10 to the inner lumen surface of the blood vessel due to the radially expansive properties of stent 28.

Stent 28 provides more than means for improved support and anchoring properties for the invention. Stent 28 also provides a support structure that is never in direct contact with a body fluid passing through the intraluminal passageway into which it is installed. Accordingly, fibrin and thrombotic deposits, common in prior art support structures which are in direct contact with the blood after implantation, are minimized.

The stent 28 may be inserted and positioned within either or both of cuffs 20 and 22 of prosthesis 10 before implantation. Alternatively, the stent may be inserted into the prosthesis via catheter after the prosthesis 10 has been implanted. If stents 28 are positioned within cuffs 20 and 22 prior to implantation then the stents may be radially compressed along with tubular conduit 12 for catheter deployment. However, as above mentioned, tubular body 12 with cuffs 20 and 22 may be intraluminally deployed first and then stents 28 may be inserted in a subsequent procedure. It is still further contemplated that in certain situations, the stents may be disposed over tubular conduit 12 such as shown in Figure 5, and then once deployed the stents may be inserted into cuffs 20 and 22.

As mentioned above, implantable tubular intraluminal prosthesis 10 may include longitudinal ribs 18 which permit prosthesis 10 to be in partially folded or radially collapsed as shown in Figure 6. Other techniques for collapsing prosthesis 10 may also be employed. In the radially collapsed state, where the tubular conduit 12 as well as cuffs 20 and 22 are collapsed, the intraluminal prosthesis 10 can negotiate curves or bends of a blood vessel or other body passageway in which it is implanted and transported. The device may be inserted percutaneously (in its collapsed state) by use of a delivery catheter (not shown) and directed to a target area by any means or method known to those skilled in the art. When positioned, stent 28 and tubular conduit 12 are then radially expanded to return to the condition shown in Figures 4 and 5. Radial expansion of both conduit 12 and stents 28 may be accomplished with assistance of, for example, an expandable catheter balloon. It is also contemplated that the conduit 12 as well as stents 28 may be constructed to be radially self-expanding after deployment.

As stents 28 are contained within the slots 24 and 26 outside the lumen of intraluminal prosthesis 10, the prosthesis has an almost infinitely variable and adjustable diameter in the ranges between the minimum and maximum diameter of the tubular conduit 12. Thus, the inner diameter of the lumen of the vessel in which the device is inserted need not be exactly known or predetermined.

Referring to Figure 7, stent 28 is designed to radially expand with the force sufficient enough to anchor prosthesis 10 within a lumen 32 of a vessel 34 to form a liquid seal therein without placing disruptive force or undue pressure on the intraluminal walls. If it is determined that a more appropriately sized stent is necessary for a proper seal after insertion, the stent can be easily removed and replaced within the cuff by a better fitting stent without first excising the prosthesis. As the cuffs are generally flexible and complaint, they may accom-

modate a range of stent sizes as may be dictated by the particular application.

Stent 28 is shown clearly supported in slot 24. Because the stent is enclosed between the prosthesis material of tubular body 12 and cuff material 20, the stent 28 is never in direct contact with either blood flowing through lumen 32 or the tissue of the walls of vessel 34. This is a marked improvement over conventional methods of using stents, normally attached using hooks or sutures directly to the luminal walls.

As mentioned above, while the preferred embodiment of the present invention shows an endoprosthesis which is used to reinforce or buttress a body lumen, it is also contemplated that the present invention may be practiced with a tubular graft which may be used to replace a missing section of a body lumen such as a blood vessel.

Thus, while the above embodiments have been disclosed, other and further manifestations of the present invention will become apparent to those skilled in the art. It is intended to claim all such changes and modifications which come within the true scope and spirit of the present invention.

Claims

1. An implantable prosthesis comprising:
   a tubular conduit having an elongate body and opposed open ends, the conduit being capable of radial diametrical change between a first diameter and a second diameter;
   an elongate cuff formed at one end region of the body; and
   a variable diameter generally annular stent supported by the cuff.

2. An implantable prosthesis according to claim 1, wherein the cuff defines a partial enclosure with the body for enclosing the stent.

3. An implantable prosthesis according to claim 1 or 2, wherein the cuff has a closed end and an open end, thereby defining a slot for insertable accommodation of the stent.

4. An implantable prosthesis according to claim 1, 2 or 3, wherein the tubular conduit includes a plurality of longitudinal ribs to permit radial contraction from the first diameter to the second diameter, in order to provide for intraluminal deployment.

5. An implantable prosthesis according to any preceding claims, wherein the tubular conduit is formed of a textile fabric.

6. An implantable prosthesis according to any one of claims 1 to 4, wherein the tubular conduit is formed from polytetrafluoroethylene.

7. An implantable prosthesis according to any preceding claim, wherein the cuff is integrally formed with the tubular conduit.

8. An implantable prosthesis according to claim 7, wherein the one end of the tubular conduit is folded externally over the body.

9. An implantable prosthesis according to claim 7 wherein the one end of the tubular conduit is folded externally over the body.

10. An implantable prosthesis according to any preceding claim, wherein the other end of the tubular conduit includes a cuff.

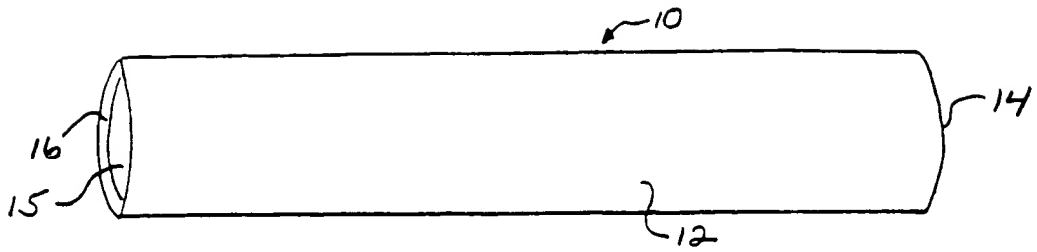

FIG 1

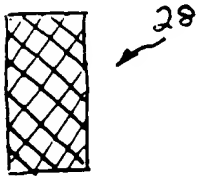

FIG2

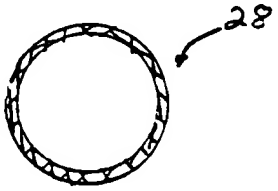

FIG 3

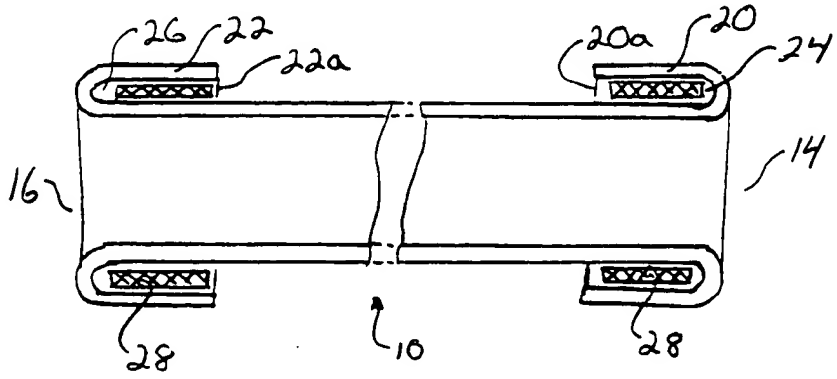

FIG 4

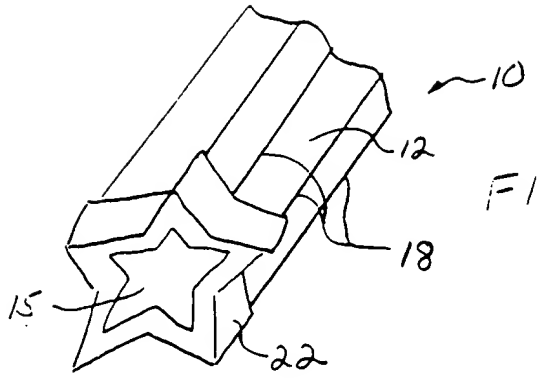

FIG 6

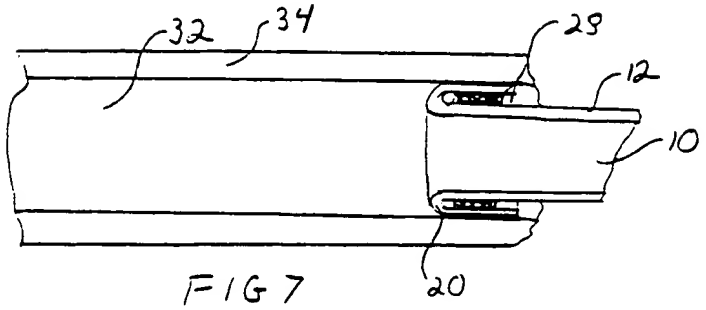

FIG 7

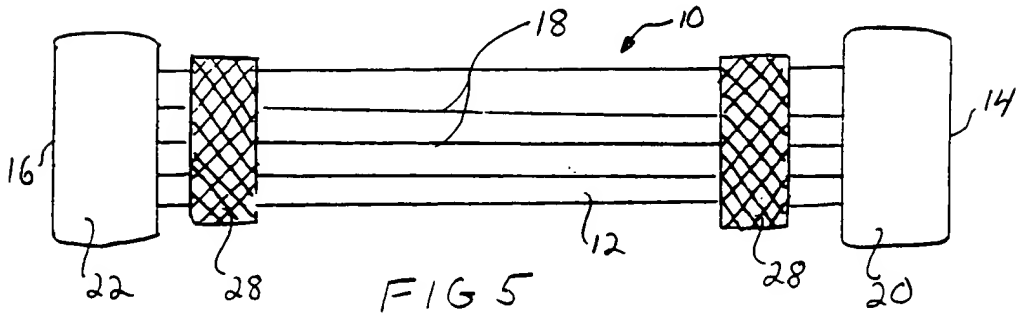

FIG 5

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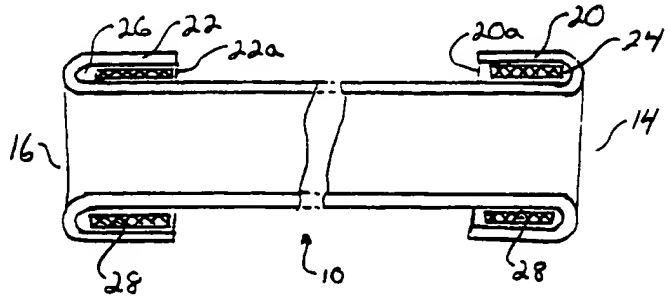

FIG 4

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EUROPEAN SEARCH REPORT

Application Number
EP 95 30 3233

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	WO 94 01056 A (BOSTON SCIENT CORP) 20 January 1994 * page 14, line 24 - line 33; figures 5,5A * ---	1,2,5, 7-10	A61F2/06
A	EP 0 579 523 A (CELSA L G SA ;ANIDJAR SAMY DOCTEUR (FR)) 19 January 1994 * column 6, line 49 - column 7, line 12; figure 11 * ---	1,2,7-9	
A	US 5 123 917 A (LEE PETER Y) 23 June 1992 * claim 1; figures 1-5 * ---	1	
A	DE 39 18 736 A (VALLBRACHT CHRISTIAN DR) 13 December 1990 * claims 1,2,6; figure 4 * -----	1,4,6	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	17 April 1997	Kanal, P

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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